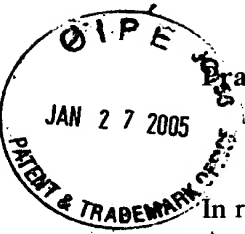


01-28-05

AF 1614  
JFE



Practitioner's Docket No. U 012951-1

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: Chun-Ying HUANG, et al  
Application No.: 09/768,442  
Filed: January 24, 2001  
For: PHARMACEUTICAL COMPOSITION FOR THE TREATMENT OF HEPATOCELLULAR CARCINOMA

Group No.: 1614  
Examiner: Michael G. Hartley

Commissioner for Patents  
P. O. Box 1450  
Alexandria, VA 22313-1450

TRANSMITTAL OF INFORMATION DISCLOSURE STATEMENT  
BEFORE MAILING DATE OF EITHER A FINAL ACTION  
OR NOTICE OF ALLOWANCE (37 C.F.R. 1.97(c))

NOTE: 37 C.F.R. 1.97: "(c) An information disclosure statement shall be considered by the Office if filed after the period specified in paragraph (b) of this section, provided that the information disclosure statement is filed before the mailing date of any of a final action under § 1.113, a notice of allowance under § 1.311, or an action that otherwise closes prosecution in the application, and it is accompanied by one of:

- (1) The statement specified in paragraph (e) of this section; or
- (2) The fee set forth in § 1.17(p)."

NOTE: "If a final action or notice of allowance is mailed in an application and later withdrawn, the application will be considered as not having had a final action or notice of allowance mailed for purposes of considering an information disclosure statement." Notice of April 20, 1992 (1138 O.G. 37-41, 39).

CERTIFICATION UNDER 37 C.F.R. 1.8(a) and 1.10\*  
(When using Express Mail, the Express Mail label number is **mandatory**;  
Express Mail certification is optional.)

I hereby certify that, on the date shown below, this correspondence is being:

MAILING

☐ deposited with the United States Postal Service in an envelope addressed to the Commissioner for Patents, P. O. Box 1450, Alexandria, VA 22313-1450.

37 C.F.R. 1.8(a)

37 C.F.R. 1.10\* (Preferred)

☐ with sufficient postage as first class mail.

☒ as "Express Mail Post Office to Address"  
Mailing Label No. EV 481672570 US (mandatory)

TRANSMISSION

☐ transmitted by facsimile to the Patent and Trademark Office to (703) 872-9306

Date: January 27, 2005

Signature  
CONNIE YANNUZZI  
(type or print name of person certifying)

\* Only the date of filing (§ 1.6) will be the date used in a patent term adjustment calculation, although the date on any certificate of mailing or transmission under § 1.8 continues to be taken into account in determining timeliness. See §

1.703(f). Consider "Express Mail Post Office to Addressee" (§ 1.10) or facsimile transmission (§ 1.6(d) for the reply to be accorded the earliest possible filing date for patent term adjustment calculations.

**NOTE:** 37 C.F.R. § 1.704(d): "A paper containing only an information disclosure statement in compliance with §§ 1.97 and 1.98 will not be considered a failure to engage in reasonable efforts to conclude prosecution (processing or examination) of the application under paragraphs (c)(6), (c)(8), (c)(9), or (c)(10) of this section if it is accompanied by a statement that each item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart application and that this communication was not received by any individual designated in § 1.56(c) more than thirty days prior to the filing of the information disclosure statement. This thirty-day period is not extendable."

**NOTE:** "If information submitted during the period set forth in 37 C.F.R. 1.97(c) with a certification is used in a new ground of rejection on unamended claims, the next Office action will not be made final since in this situation it is clear that applicant has submitted the information to the office promptly after it has become known and the information is being submitted prior to a final determination on patentability by the Office. However, the information submitted with a certification can be used in a new ground of rejection and the next Office action made final, [i]f the new ground of rejection was necessitated by amendment of the application by applicant. Where the information is submitted during this period with a fee, the examiner may use the information submitted, e.g., printed publication or evidence of public use, and make the next Office action final whether or not the claims have been amended, provided that no other new ground of rejection which was not necessitated by amendment to the claims is introduced by the examiner. See MPEP 706.07(a). If a new ground of rejection is introduced that is neither necessitated by an amendment to the claims nor based on the information submitted with the fee set forth in 37 C.F.R. 1.17(p), the Office action shall not be made final. Notice of April 20, 1992 (1138 O.G. 37-41, 39).

**WARNING:** "A petition for suspension of action to allow applicant time to submit an information disclosure statement will be denied as failing to present good and sufficient reasons, since 37 C.F.R. 1.97 provides adequate recourse for the timely submission of prior art for consideration by the examiner." Notice of July 6, 1992 (1141 O.G. 63). But see § 103(b) and (c), limited suspension of action in a continued prosecution application (CPA) filed under § 1.53(d) and in a request for continued examination (RCE) under § 1.114.

**WARNING:** No extension of time can be had under 37 C.F.R. 1.136(a) or (b) for filing an IDS. 37 C.F.R. 1.97(f).

### TIME OF TRANSMITTAL OF ACCOMPANYING INFORMATION DISCLOSURE STATEMENT

1. The information disclosure statement transmitted herewith is being filed **after** three months of the filing date of this national application or the date of entry of the national stage as set forth in § 1.491 in an international application or after the mailing date of the first Office action on the merits, whichever event occurred last but **before** the mailing date of either:

- (1) a final action under § 1.113 or
- (2) a notice of allowance under § 1.311,

whichever occurs first.

### STATEMENT OR FEE

2. Accompanying this transmittal is  
(check either A or B below)

A. ☒ a statement as specified in 37 C.F.R. 1.97(e).

OR

B. ☐ the fee set forth in 37 C.F.R. 1.17(p) for submission of an information disclosure statement under § 1.97(c). (\$180.00).

**METHOD OF PAYMENT OF FEE**

3.

- ☐ Attached is a check in the amount of \$ \_\_\_\_\_.
- ☐ Charge Account No. \_\_\_\_\_ in the amount of \$ \_\_\_\_\_.
- A duplicate of this request is attached.

If any additional or lesser fees are due, please charge or refund deposit Account 12-0425.

Reg. No. 33,778

Tel. No.: (212 ) 708-1935

Customer No.: 00140

  
**SIGNATURE OF PRACTITIONER**

Janet I. Cord  
(type or print name of practitioner)

\_\_\_\_\_  
P.O. Address

\_\_\_\_\_  
c/o Ladas & Parry LLP  
26 West 61<sup>st</sup> Street  
New York, N.Y. 10023



**PATENT**

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re application of: Chun-Ying **HUANG**, et al

Serial No.: 09/768,442

Group No. 1614

Filed: January 24, 2001

Examiner: Michael G. Hartley

For: **PHARMACEUTICAL COMPOSITION FOR THE TREATMENT OF  
HEPATOCELLULAR CARCINOMA**

Attorney Docket No.: U 012951-1

Commissioner for Patents  
P. O. Box 1450  
Alexandria, VA 22313-1450

**INFORMATION DISCLOSURE STATEMENT**

WO99/61085 was cited in an Office Action dated November 22, 2004 in the  
corresponding application in Taiwan.

**CERTIFICATION UNDER 37 C.F.R. 1.8(a) and 1.10\***

*(When using Express Mail, the Express Mail label number is **mandatory**;  
Express Mail certification is optional.)*

I hereby certify that, on the date shown below, this correspondence is being:

**MAILING**

- ☒ deposited with the United States Postal Service in an envelope addressed to the Commissioner for Patents, P. O. Box 1450, Alexandria, VA 22313-1450.

**37 C.F.R. 1.8(a)**

- ☒ with sufficient postage as first class mail.

**37 C.F.R. 1.10\***

- ☐ as "Express Mail Post Office to Addressee"  
Mailing Label No. \_\_\_\_\_  
(mandatory)

**TRANSMISSION**

- ☐ transmitted by facsimile to the Patent and Trademark Office. to (703) 872-9306

Date: January 27, 2005

*(Signature)*  
CONNIE GANNOTT

(type or print name of person certifying)


**\*WARNING:** Each paper or fee filed by "Express Mail" **must** have the number of the "Express Mail" mailing label placed thereon prior to mailing. 37 C.F.R. 1.10(b).  
"Since the filing of correspondence under § 1.10 without the Express Mail mailing label thereon is an oversight that can be avoided by the exercise of reasonable care, requests for waiver of this requirement will **not** be granted on petition." Notice of Oct. 24, 1996, 60 Fed. Reg. 56,439, at 56,442.

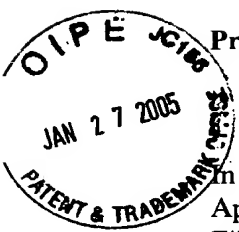
Form PTO-1449 is attached with reference copy.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Janet I. Cord", written over a horizontal line.

Janet I. Cord  
c/o Ladas and Parry LLP  
26 West 61<sup>st</sup> Street  
New York, NY 10023  
Reg. No. 33,778, (212) 708-1935

FORM PTO-1449		U. S DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE		ATTY. DOCKET NO.		SERIAL NO.	
				U 012951-1		09/768,442	
 <p style="text-align: center;">INFORMATION DISCLOSURE STATEMENT BY APPLICANT</p> <p>(Use several sheets if necessary)</p>		APPLICANT					
		Chun-Ying HUANG, et al					
		FILING DATE			GROUP		
		January 24, 2001			1614		
U.S. PATENT DOCUMENTS							
EXAMINER INITIALS	REFERENCE DESIGNATION	DOCUMENT NUMBER	DATE	NAME		FILING DATE IF APPROPRIATE	
	AA						
	AB						
	AC						
	AD						
	AE						
	AF						
	AG						
	AH						
	AI						
	AJ						
	AK						
FOREIGN PATENT DOCUMENTS							
		DOCUMENT NUMBER	DATE	COUNTRY		TRANSLATION	
						YES	NO
	AL	99/61085	12/1999	WO			
	AM						
	AN						
	AO						
	AP						
OTHER ART (Including Author, Title, Date, Pertinent Dates, Etc.)							
	AR						
	AS						
	AT						
EXAMINER				DATE CONSIDERED			
EXAMINER:		Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.					



Practitioner's Docket No. U 012951-1

**PATENT**

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re application of: Chun-Ying HUANG, et al

Application No.: 09/768,442

Group No.: 1614

Filed: January 24, 2001

Examiner: Michael G. Hartley

For: **PHARMACEUTICAL COMPOSITION FOR THE TREATMENT OF HEPATOCELLULAR CARCINOMA**

**Commissioner for Patents  
P. O. Box 1450  
Alexandria, VA 22313-1450**

**STATEMENT FOR INFORMATION DISCLOSURE UNDER 37 C.F.R. SECTION 1.97(e)**

**NOTE:** A statement must state either: "(1) that each item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement, or (2) that no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application and to the knowledge of the person signing the statement after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in Section 1.56(c) more than three months prior to the filing of the information disclosure statement." 37 C.F.R. Section 1.97(e).

*Under the first statement under § 1.97(e), it does not matter whether any individual with a duty of disclosure actually knew about any of the information cited before receiving the search report. The date on the communication by the foreign patent office begins the 3-month period in the same manner as the mailing of an Office action starts a 3-month shortened statutory period for reply. See § 609B(5), M.P. E. P., 8<sup>th</sup> Edition.*

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**CERTIFICATION UNDER 37 C.F.R. 1.8(a) and 1.10\***

*(When using Express Mail, the Express Mail label number is **mandatory**;  
Express Mail certification is optional.)*

I hereby certify that, on the date shown below, this correspondence is being:

**MAILING**

- ☐ deposited with the United States Postal Service in an envelope addressed to the Commissioner for Patents, P. O. Box 1450, Alexandria, VA 22313-1450.

**37 C.F.R. 1.8(a)**

- ☐ with sufficient postage as first class mail.

**37 C.F.R. 1.10\***

- ☒ as "Express Mail Post Office to Addressee"  
Mailing Label No. EV 481672570 US  
(mandatory)

**TRANSMISSION**

- ☐ transmitted by facsimile to the Patent and Trademark Office. to **(703) 872-9306**

Date: January 27, 2005

  
Signature

CHRISTINE L. FAWCETT  
(type or print name of person certifying)

*• Only the date filing (§ 1.6) will be the date used in a patent term adjustment calculation, although the date on any certificate of mailing or transmission under § 1.8 continue to be taken into account in determining timeliness. See § 1.703(f). Consider "Express Mail Post Office to Addressee" (§ 1.10) or facsimile transmission (§ 1.6(d)) for the reply to be accorded the earliest possible filing date for patent term adjustment calculations.*

NOTE: "Section 1.97(e) makes it clear that a certification could contain either of two statements. One statement is that each item of information in an information disclosure statement was cited in a search report from a patent office outside the U.S. not more than three months prior to the filing date of the statement. Under this certification, it would not matter whether any individual with a duty actually knew about any of the information cited before receiving the search report. In the alternative, the certification could state that no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application or, to the knowledge of the person signing the certification after making reasonable inquiry, was known to any individual having a duty to disclose more than three months prior to the filing of the statement." Notice of January 9, 1992, 1135 O.G. 13-25, at 13. (emphasis added). Thus: "If an item of information is submitted within three months of being cited in a communication from a foreign patent office in a counterpart foreign application, the certification can be properly made regardless of any individual's previous knowledge of the information." *Id.*, 1135 O.G. at 19. See § 609B(5), M.P.E.P., 8<sup>th</sup> Edition.

NOTE: "The date on the communication by the foreign patent office begins the 3-month period in the same manner as the mailing of an Office action starts a 3-month shortened statutory period for reply. If the communication contains two dates, the mailing date of the communication is the one which begins the 3-month period. The date which begins the 3-month period is not the date the communication was received by a foreign associate or the date it was received by a U.S. registered practitioner. Likewise, the statement will be considered to have been filed on the date the statement was received in the Office, or on an earlier date of mailing or transmission if accompanied by a properly executed certificate of mailing or facsimile transmission under 37 C.F.R. 1.8, or if it is in compliance with the provisions for "Express Mail" delivery under 37 C.F.R. 1.10." See § 609B(5), M.P.E.P., 8<sup>th</sup> Edition.

NOTE: "The certification can be based on present, good faith knowledge about when information became known without a search of files being made." Thus,, for example, the certification of § 1.97(e) does not preclude the use of the certification in an application by corporations whose practitioners have over the years reviewed thousands of patents and technical publications even though they are unaware of the relevance of any one thereof to the application. Notice of January 9, 1992, 1135 O.G. 13-15, at 19.

See § 609B(5), M.P.E.P., 8<sup>th</sup> Edition:

*"If an information disclosure statement includes a copy of a dated communication from a foreign patent office which clearly shows that the statement is being submitted within 3 months of the date on the communication, the copy will be accepted as the required communication. It will be assumed, in the absence of evidence to the contrary, that the communication was for a counterpart foreign application.*

*In the alternative, a statement can be made if no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application and, to the knowledge of the person signing the statement after making reasonable inquiry, neither was it known to any individual having a duty to disclose more than 3 months prior to the filing of the statement."*

NOTE: A copy of the foreign search report need not be submitted with the certification. Notice of April 20, 1992 (1138 O.G. 37-41, 40).

NOTE: "The phrase 'after making reasonable inquiry' makes it clear that the individual making the certification has a duty to make reasonable inquiry regarding the facts that are being certified. The certification can be made by a registered practitioner who represents a foreign client and who relies on statements made by the foreign client as to the date the information first became known. A registered practitioner who receives information from a client without being informed whether the information was known for more than three months, however, cannot make the certification without making reasonable inquiry. For example, if an inventor gave a publication to the attorney prosecuting an application with the intent that it be cited to the Office, the attorney should inquire as to when that inventor became aware of the publication and should not submit a certification under 37 C.F.R. 1.97(e)(2) to the Office until a satisfactory response is received. The certification can be based on present, good faith knowledge about when information became known without a search of files being made." Notice of April 20, 1992 (1138 O.G. 37-41, 39).

See § 609B(5), M.P.E.P., 8<sup>th</sup> Edition.

NOTE: "Although it is recognized that an individual actually becomes aware of the information in the communication from a foreign patent office sometime after it was mailed, the mailing date of such a communication, if it occurs prior to a first awareness of the same information, would determine the date for filing of an information disclosure statement without a fee" in a certification procedure under Section 1.97(e). Notice of January 9, 1992, 1135 O.G. 13-25, at 19 (emphasis added).

NOTE: The mere absence of an item of information for a foreign patent office communication is not intended to



represent an opportunity to delay the submission of a item known more than three months prior to the filing of an information disclosure statement to an individual having the duty of disclosure under Section 1.56. 62 Fed. Reg. 53,131, 53,150 (Oct. 10, 1997).

NOTE: The IDS is considered filed as of the date it is received in the PTO, or on an earlier date of mailing of transmission if done so with a properly executed certificate of mailing or facsimile transmission under 37 C.F.R. § 1.8, or if it is in compliance with the provisions for "Express Mail" delivery under 37 C.F.R. § 1.10. See § 609B(5), M.P.E.P., 8<sup>th</sup> Edition.

NOTE: "The certification under Section 1.97(e) should be made by a person who has knowledge of the facts being certified. The certification can be made by a practitioner who represents a foreign client and who relies on statements made by the foreign client as to the date the information first became known. A practitioner who receives information from a client without being informed whether the information was known for more than three months, however, cannot make the certification without making reasonable inquiry." Notice of January 9, 1992, 1135 O.G. 13-25 at 19.

NOTE: "The term counterpart foreign patent application means that a claim for priority has been made in either the U.S. application or a foreign application based on the other, or that the disclosures of the U.S. and foreign patent applications are substantively identical (e.g., an application filed in the European Patent Office claiming the same U.K. priority as claimed in the U.S. application)." Notice of April 20, 1992 (1138 O.G. 37-41, 39).

NOTE: "Individuals other than the attorney, agent or inventor may comply with this section by disclosing information to the attorney, agent or inventor." 37 C.F.R. Section 1.56(d) and

"Individuals associated with the filing or prosecution of a patent application within the meaning of this section are:

- (1) each inventor named in the application;
- (2) each attorney or agent who prepares or prosecutes the application; and
- (3) every other person who is substantively involved in the preparation or prosecution of the application and who is associated with the inventor, with the assignee or with anyone to whom there is an obligation to assign the application." 37 C.F.R. Section 1.56(e).

## IDENTIFICATION OF INFORMATION DISCLOSURE STATEMENT FOR WHICH THIS STATEMENT IS BEING MADE

1. This statement is being made for the Information Disclosure Statement  
[ X ] accompanying this statement.  
[ ] filed \_\_\_\_\_  
Date

## STATEMENT

2. I, the person(s) signing below state:

that each item of information contained in the information disclosure statement was **first** cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. 37 C.F.R. Section 1.97(e)(1).

NOTE: The three month period starts from the mailing date of the foreign patent office communication. Notice of January 9, 1992, 1135 O.G. 13-25 at 19. The mailing date is the "date on the communication by the foreign patent office." Notice of April 20, 1992 (1138 O.G. 37-41, 39).

## OR

that no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application and to the knowledge of the person signing the statement after making reasonable inquiry, was known to any individual designated in Section 1.56(c) more than three months prior to the filing of the

information disclosure statement. 37 C.F.R. Section 1.97(e)(2).

NOTE: "The time at which information 'was known to any individual designated in 37 C.F.R. 1.56(c)' is the time when the information was discovered in association with the application even if awareness of the materiality came later." Notice of April 20, 1992 (1138 O.G. 37-41, 40).

### IDENTIFICATION OF PERSON(S) MAKING THIS STATEMENT

3. The person making this statement is

*(check each applicable item)*

(a) ☐ the inventor(s) who signs below

\_\_\_\_\_  
**SIGNATURE OF INVENTOR**

\_\_\_\_\_  
*(type name of inventor who is signing)*

(b) ☐ a person who is substantively involved in the preparation or prosecution of the application, and who is associated with the inventor, with the assignee, or with anyone to whom there is an obligation to assign the application (37 C.F.R. Section 1.56(c)) and who signs below.

\_\_\_\_\_  
**SIGNATURE OF PERSON MAKING STATEMENT**

\_\_\_\_\_  
*(type name of person who is signing)*

\_\_\_\_\_  
Address of person who is signing

(c) ☒ the practitioner who signs below on the basis of the information:

*(check each applicable item)*

- ☐ supplied by the inventor(s).
- ☒ supplied by an individual designated in Section 1.56(c).
- ☒ in the practitioner's file.

  
\_\_\_\_\_  
**SIGNATURE OF PRACTITIONER**

**Janet I. Cord**

\_\_\_\_\_  
*(type or print name of practitioner)*

\_\_\_\_\_  
P.O. Address

\_\_\_\_\_  
c/o Ladas & Parry LLP  
26 West 61<sup>st</sup> Street  
New York, N.Y. 10023

Reg. No. 33,778

Tel. No. (212) 708-1935

Customer No.: 00140